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| EXAMINER |
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MATTER, KRISTEN CLARETTE

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| ART UNIT | PAPER NUMBER |
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08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/524,632 | Applicant(s) NAWATA, HIDEO | |
| | Examiner KRISTEN C. MATTER | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the amendment filed 5/20/2009. Claims 1-5 have been amended, claims 6-8 have been added, and no claims have been cancelled. Currently, claims 1-8 are pending in the instant application.

Claim Rejections - 35 USC § 102/35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gropper et al. (US 5,540,220). Gropper et al. discloses an oxygen supplying apparatus comprising a respiration sensor (40) which detects the respiration of the user and provides a respiration signal, a supply method setting means (98) which selects the supply in continuous flow or in synchronism with the user (see column 5, line 41 and column 17, lines 33-36 also, which implies that the system is capable of being set in a variety of continuous flow modes by manual selection of the user; the supply method setting means is then carried out by the assist module if turned on and available during a given time in the cycle), a flow rate setting means (78) for supply of a set value for flow rate that is entirely independent of the supply method setting means, and a controlling means (46) that controls the aperture of a single automatic closing valve (68) corresponding to the supply flow rate set value by receiving a supply method setting signal of the continuous flow, or opens the automatic closing valve on the inhalation starting point based on the respiration signal by receiving a supply method setting signal of the synchronous flow and at the same time controls the open

Art Unit: 3771

time of the automatic closing valve corresponding to the flow set rate value, wherein the closing valve is controlled by the controlling means which had taken the information set by the supply method (assist trigger signal) and the flow rate setting means (see column 8, lines 40-60 and column 17, lines 5-31).

Gropper et al. does not specifically disclose an oxygen generating means (examiner notes however that the oxygen generating means is part of the preamble only and does not appear to give much patentable weight to the claims). However, oxygen generating means are well known and commonly used for supplying oxygen to patients in breathing devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used oxygen generating means as the “conventional pressurized [oxygen] source” of Gropper et al. in order to supply oxygen to the patient without the need of pure oxygen cylinders, for example. Furthermore, it appears as though the device of Gropper et al. would perform equally well with an oxygen generating means/supply.

Claim Rejections - 35 USC § 103

Claims 2, 3, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gropper et al. in view of admitted prior art (instant specification, page 10). Gropper et al. is silent as to the response time and diameter of the closing valve. However, applicant admits on page 10 of the specification that these types of valves are well known and commonly used in the art (i.e., since the claimed automatic closing valve is commercially available). Therefore, it would have been obvious to one of ordinary skill in the art to use a closing valve with a response time of less than 0.1 seconds and a diameter of 1-5 mm as taught by the admitted prior art in

Art Unit: 3771

order to allow the desired flow rates to be delivered to a patient more efficiently and safely (i.e., a valve with a quicker response time would allow more precise control over the opening and closing of the valve and thus, more accurate delivery of a desired air flow to the patient).

Furthermore, using a commercially available valve in a similar system to the claimed invention would yield predictable results that do not patentably distinguish an invention over the prior art of record. Nor does a mere change in dimension without a change in function or unexpected result patentably distinguish the invention over the prior art. Because of the absence of a critical teaching and/or a showing of unexpected results from having the closing valve have a response time of 0.1 seconds or less and a diameter of 1-5 mm and the fact that the flow rates to be delivered in the instant application and the prior art are similar, it appears as though the device of Gropper et al. would perform equally well with the claimed closing valve response time and dimensions.

Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gropper et al. Gropper et al. does not specifically disclose an adsorption-type oxygen generating means. However, pressure variable adsorption-type oxygen concentrating means provided with adsorption cylinders packed with adsorbent that adsorbs nitrogen rather than oxygen are well known and commonly used for supplying oxygen to patients in breathing devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an adsorption-type oxygen generating means as the “conventional pressurized [oxygen] source” of Gropper et al. in order to supply oxygen to the patient without the need of pure oxygen cylinders, for example. Furthermore, it appears as

Art Unit: 3771

though the device of Gropper et al. would perform equally well with an adsorption-type oxygen generating means/supply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/569,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claim 1 is a broader version of the copending claim 8 (i.e. the instant claim 1 does not include the structural element of the exhaust means or pressure measuring means as in the copending claim 8). In the instant claim 1, the structural elements are included in the copending claim 8. Any infringement over the copending

Art Unit: 3771

application would also infringe over the instant claims. Hence, the instant claims 1-8 do not differ from the scope of the copending claims 1-14.

Response to Arguments

Applicant's arguments filed 5/20/2009 have been fully considered but they are not persuasive.

In response to applicant's argument that Gropper et al. does not disclose a "single" automatic closing valve, examiner respectfully disagrees. Flow rate selection valve (68) is described as an automatic closing valve that is opened and closed via a set of commands from the controller as discussed in the above rejection. The valve (68) is referred to as a "valve" not more than one valve in the reference just because it has multiple automatic closing orifices (i.e., 3-way valves are often also still considered a single valve). The fact that another separate valve (72) is used in addition to the flow rate valve (68) in Gropper et al. to arrive at the desired flow rate does not patentably distinguish the invention because there is no limitation in the claims that the single automatic closing valve operates alone to arrive at the final desired flow rate (i.e., the automatic closing valve orifices of Gropper et al. are either fully opened or fully closed upon a received signal and the separate variable orifice valves (78, 80) control the final flow rate according to the manual input, both the automatic closing valve and variable orifice valves are needed to get the desired air flow to the patient). Alternatively, one could also look at just one of the orifices of the flow rate selection valve 68 (i.e., the inspiratory flow branch) and consider that as the automatic closing valve because it is in itself opened and closed according to the above control parameters.

Art Unit: 3771

In response to applicant's argument that examiner lacks sufficient reasoning for using a valve with the claimed response time and dimensions, examiner notes that there is nothing in the claims indicating what structure allows the claimed response time and again points to the fact that the claimed valve is commercially available as admitted by applicant. Valves are a common feature in the ventilator/respirator art and one of ordinary skill in the art would be familiar with commercially available automatic valves used in these types of systems. Thus, one of ordinary skill would recognize that smaller, quicker response times in valves are desirable in order to provide more precise control of air flow to the patient as discussed above (reduction of overall dimensions/weight of a medical device is also often a desired feature). Furthermore, absent a critical teaching and/or showing of unexpected results, examiner contends that use of a well known valve in a well known system would yield predicted results that do not patentably distinguish an invention over the prior art of record.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, as discussed above, use of a commercially available valve that would give increased precision with the delivery of oxygen is well within the knowledge of one of ordinary skill in the art.

Art Unit: 3771

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4681099, US 4822384, and US 3221734 are cited to show other automatically controlled ventilators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771